

II. Remarks

A. Introduction

Reconsideration and allowance of the present application are respectfully requested.

Claims 1, 2, 4, 5, 10-12, 16-23, 25, 26, 28, 30-36, 38, 39, and 42-45 are pending in the present application. Claims 1, 25, 30 and 39 are independent.

B. Claim Rejections under 35 U.S.C. § 103(a)

1. The Combination of Muchin and Edwards Fails to Suggest the Claimed Invention

Independent Claims 1, 25, 30, and 39, as well as dependent Claims 2, 4, 5, 10-12, 16-20, 22, 23, 25, 28, 30, 31, 39 and 42-45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,241,998 to Muchin (hereinafter “Muchin”) in view of U.S. Patent No. 6,037,280 to Edwards et al. (hereinafter “Edwards”). Applicant traverses the rejection based on the Declaration under 37 C.F.R. § 1.132 filed herewith, and the following arguments.

To reject a claim under Section 103(a), the Patent Office must establish a *prima facie* case of obviousness that requires “consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991); see also *Dystar Textilfarben GmbH & Co. Deutschland Kg v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). It is improper to merely identify elements in various cited references, because doing so “would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.” See *In re Rouffet*, 149 F.3d 1350, 1357-58 (Fed. Cir. 1998); See *Dennison Manufacturing Company v. Panduit Corp.*, 475 US 809, 229 USPQ 478, 479 (1986) (one “must not pick and choose isolated elements from the prior art and combine them so as to yield the invention in question if such a combination would not have been obvious at the time of the invention.”). “It is impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” See *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). Picking and choosing among selected teachings in the prior art is a form of improper hindsight reconstruction. See *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir.

1988).

Furthermore, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

As explained on page 1, lines 45 of the present application, this invention relates to a patch, kit or method for reducing exposure of skin to UV radiation and mentions on page 1, lines 9 to 11 that it is important to protect individuals from sunlight due to the deleterious cosmetic and medical effects of sunlight on skin and subcutaneous tissues. Some of the medical conditions that are related to exposure to sunlight are incredibly serious conditions, and include cancer. In fact, it is mentioned on page 3, lines 6 to 7 that "the medical consensus is that there is strong evidence to support the assertion skin cancers are caused by damage from UV rays in sunlight" and this is confirmed by the expert in paragraph 5 of the enclosed Declaration of Professor Sir Alexander Markham under 37 C.F.R. § 1.132. It is also mentioned in the application that certain types of skin moles are likely to develop into melanoma (see page 4, paragraph 1).

It is therefore clear that the skilled person is a medical practitioner skilled in the art of developing medical products for the prevention of skin cancer since this is the whole point of the present invention.

In contrast to the present invention, Muchin et al relates to a dermatological patch for removing keratotic plugs. Muchin teaches a dermatological patch for removing keratotic plugs (commonly known as blackheads) upon the application and removal of the patch from the skin to improve the health and appearance of skin. (*See* Muchin, 2:51-53.) The patch has an adhesive surface such that the entire engaging surface of the patch wholly adheres with the skin. (*Id.* 3:41-5.) In operation, a user applies the patch to the skin having keratotic plugs (typically on the user's face) with the adhesive surface, such that the adhesive is in direct contact with the skin. (*Id.* 7:63-8:1.) The user then waits a prescribed amount of time (i.e., temporarily), such that the adhesive composition can bond to the keratotic plugs, and the patch is pulled from the skin, thereby removing the keratotic plugs. (*Id.*, 8:1:8.) Thus, Muchin's patch is not designed to be kept on the skin for a prolonged period of time. The patch is intended for removing unwanted

keratotic plugs from the skin, not for adding protection to the skin. The examiner considers that the disclosure of the zinc oxide as a possible pigment for the polymeric adhesive composition on column 4, line 35 is relevant to claim 1 of the present application which requires at least one of the first or second layers to be opaque to a UV radiation wherein the UV radiation is UVA and UVB. However, the expert considers that the zinc oxide present in the pigment of the patch of Muchin et al would not have any effect on the prevention of UVA and UVB light exposure to the skin underneath. (See Declaration of Professor Sir Alexander Markham under 37 C.F.R. § 1.132). The reason for this being that the patch is put on temporarily to remove the blackhead and would be conducted in the privacy of one's home (an environment typically not associated with high UVA and UVB levels) as confirmed under paragraph 7 of the enclosed Declaration. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in protecting moles or the like by adding UV protections to a patch that is meant to be used indoor.

Furthermore, our expert considers that a skilled man in the art or a clinician looking to prevent UVA and UVB penetration to a mole or the like would simply not look at Muchin et al for any guidance. The patch of Muchin et al, in removing the keratotic plugs, would also lead to the removal of surface dermal cells. It would not be desirable to actively remove surface dermal cells from either the mole itself or for example an area of actinic keratosis.

For these reasons, Applicant does not consider that Muchin et al is relevant to the assessment of the obviousness of the claims.

Turning now to Edwards et al, this document relates to fabrics such as nylons, acrylics, acetates, polyesters, Dacron, Lycra, Spandex, cotton, rayon, wool, silk, polyethylene and polypropylene [column 2 lines 31-33] to form articles such as clothing, awnings, umbrellas, sunscreens, tents, tarps and canvases [column 2 lines 17-19] rather than any kind of patch (as is required by claim 1), it follows that the teachings of Edwards may not be simply combined with Muchin since these documents are entirely incompatible – one document relates to a patch whereas the other document relates to articles such as items of clothing.

Furthermore, the claims of the present application require the patch to be transparent such that the skin is visible through the patch. It is absurd to suggest that it would be desirable or

practical to have an item of clothing that is transparent such that the skin is visible through the patch! In summary, the enclosed declaration states that:

"it is unrealistic that Edwards provides any incentive towards a transparent patch" (see paragraph 8 of the enclosed Declaration).

It follows that the combination of Muchin et al and Edwards et al does not render the claims obvious. It is not correct that the skilled person would have a reasonable expectation of success in producing the claimed invention as suggested by the Examiner. Thus, the Office Action proves no reason why the skilled artisan would consider providing UPF of Edwards to the Muchin patch because the patch in Muchin is not intended to be provide UV protection and be kept on the skin; instead it is designed to be placed on the skin and immediately removed, taking the keratotic plugs with it. Therefore, there is no requirement for a significant UV protection level to be provided by the patch. The Office Action improperly relies on hindsight and provides no credible reason as to why a person skilled in the art would modify a kerototic plug patch for UV radiation protection.

Therefore, Muchin and Edwards cannot render obvious Claims 1, 25, 30, and 39, and this rejection must be withdrawn.

C. Dependent Claims

Dependent Claims 33-36 and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view of Edwards and further in view of U.S. Publication No. 2003/0175328 to Shefer et al. ("Shefer"). Dependent Claims 21 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view of Edwards and further in view of U.S. Patent No. 5,167,649 to Zook ("Zook"). Dependent Claim 32 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view of Edward and further in view of U.S. Patent No. 6,103,275 to Seitz et al ("Seitz").

Dependent Claims 2, 4, 5, 10-12, 16-23, 26, 28, 31-36, 38 and 42-45 depend from independent Claims 1, 25, 30 and 39, respectively. Accordingly, Claims 2, 4, 5, 10-12, 16-23, 26, 28, 31-36, 38 and 42-45 incorporate the features of independent Claims 1, 25, 30 and 39, and are patentable over the cited references for at least the same reasons as independent Claims 1, 25,

30 and 39.

D. Conclusion

In view of the above remarks, it is believed that this application is in condition for allowance, and a Notice thereof is respectfully requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3536. All correspondence should continue to be directed to the below-listed address.

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